REMARKS

Claim 7 has been amended to recite that the active ingredient of the claimed dosage form is irinotecan. Claims 10 and 11 have been amended to depend directly from claim 7. Claims 4-6, 8, 9, 13-30 and 51-79 have been cancelled without prejudice.

Claims 1-3, 7, 10-12, and 32-50 are pending in the application.

Applicants provisionally elect, with traverse, the subject matter of Group I, directed to a method of inhibiting cell proliferation. Further, Applicants provisionally elect from Species I solid oral dosage forms and from Species II the antineoplastic agent irinotecan. The requirement for election between the species etoposide, paclitaxel, doxorubicin and vincristine is considered improper, *inter alia*, because all species are phase sensitive antineoplastic agents that could be used more efficaciously with frequent lower oral dosing as opposed to intermittent higher dosing by i.v.. Moreover, each species suffers from reduced oral bioavailablity due to deactivation by the PgP efflux pump. Lastly, four species do not constitute an unreasonable number under 37 C.F.R. § 1.146. Claims related to this Markush group will be presented in a divisional application. Applicants agree with the Examiner that Applicants' claims to methods of cancer treatment by administering a gastric retention dosage form or composition in accordance with the invention containing irinotecan are clearly patentably distinct from the invention of Applicants' other claims.

Claims 1-3 read on the elected species.

Applicants respectfully submit that the amendment of claim 7 makes examination of claims 1-3, 7, 10-12 and 32-50 directed to pharmaceutical dosage forms for enhanced systemic delivery of irinotecan in this application proper and not unduly burdensome. As stated in the Action, inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

materially different product or (2) the product as claimed can be used in a materially different process of using that product. MPEP § 806.05(h). Applicants are unaware of another product that is capable of being used in the practice of the method claim 1 except for Applicants' liquid composition which has been restricted from this application. The Examiner has provided no example of another composition that is capable of being used in the method of claim 1.

The Examiner has not alleged an alternative use for the dosage form of claim 7, even as originally presented. As amended, claim 7 requires that irinotecan be the active ingredient and that the dosage form remain in the patient's stomach for a prolonged period of time after ingestion. Therefore, the dosage form of claim 7 is especially adapted for use in the method of claim 1. "If the applicant either proves or provides a convincing argument that the alternative use suggested by the examiner cannot be accomplished, the burden is on the examiner to support a viable alternative use or withdraw the requirement." MPEP 806.05(h). Applicants respectfully request that, in view of the amendment to claim 7, the Examiner withdraw the restriction and examine claims 1-3, 7,10-12 and 32-50 together in this application or provide support for a viable alternative use.

Applicants further respectfully submit that searching would not be unduly burdensome since methods of inhibiting cell proliferation of Group I and pharmacetuical dosage forms of Group II are both classified in Class 424.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that claims 1-3, 7, 10-12 and 32-50 are in condition for allowance. Early and favorable action by the Examiner is earnestly solicited. If the Examiner believes that issues may be resolved by a

telephone interview, the Examiner is urged to telephone the undersigned at the number below. The undersigned may also be contacted by email at pjohnson@kenyon.com.

Respectfully Submitted,

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Marked Up Versions of Amended Claims

7. A solid pharmaceutical dosage form for enhanced systemic delivery of irinotecan [an antineoplastic agent]comprising irinotecan[, as an active ingredient, an antineoplastic agent that is capable of absorption through the lining of the stomach, jejunum or duodenum of a patient] and a gastric retention vehicle composition comprising a hydrogel, wherein the dosage form expands upon contact with gastric fluid and wherein after ingestion by a patient the gastric retention vehicle composition expands to retain the dosage form in the patient's stomach for a prolonged period of time.

10. A method of inhibiting cell proliferation in a tumor of a patient afflicted with metastatic carcinoma of the colon or rectum by orally administering a dosage form of claim 7[9] to the patient.

11. A method of inhibiting cell proliferation in a tumor of a patient afflicted with metastatic carcinoma of the colon or rectum by executing a therapeutic program of repeated oral administration of dosage forms of claim 7[9] to the patient.